DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

95384

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 29 2004

WARNING LETTER

Certified Mail
Return Receipt

Mr. Charles Manker
President and CEO
TherMatrx, Incorporated
3675 Commercial Avenue
Northbrook, Illinois 60062

Re: PMA # P000043
TMx-2000 BPH Thermotherapy System

Dear Mr. Manker:

We are writing to you because the Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) has reviewed promotional literature that your company is distributing. This literature includes brochures directed at physicians for the TMx-2000 BPH Thermotherapy System (TMx-2000) obtained at a professional meeting. The literature contains statements that promote the TMx-2000 for indications for use that have not been approved by the FDA and that suggest the TMx-2000 is safe or effective in circumstances for which FDA has not reviewed safety or effectiveness data. This literature revealed serious regulatory problems involving the TMx-2000 which cause it to be in violation of the Federal Food, Drug, and Cosmetic Act (Act).

**Background**

Your device was approved (premarket approval application P000043) on July 16, 2001. According to the FDA-approved professional labeling, the TMx-200 is a "non-surgical device for the treatment of symptomatic benign prostatic hyperplasia (BPH) in men who have a minimum prostatic urethra length of 30 mm and a total prostate volume between 30 and 100 cc." Under the authority of § 515(d)(1)(B)(ii) of the Act, 21 U.S.C. § 360e(d)(1)(B)(ii), CDRH has designated this product as a restricted device. Subject to § 502(q) of the Act, advertising of a restricted device may not be false or misleading in any particular.

**Promotion of New Intended Uses**

From a review of the promotional material for this product, we have identified the following instances of promotion of the device for a new intended use:

1. The promotional material states that the TMx-2000 "Treats Enlarged Median Lobe." Your PMA submission does not contain clinical data to support the use of your device to treat median lobe enlargement of the prostate. The new indication is a significant modification in the intended use of the TherMatrx BPH Thermotherapy System, TMX-2000, requiring submission of a PMA supplement. 21 CFR § 814.39(a)(1).

2. We also note your literature states that treating physicians can "see other patients during treatment" with the TMx-2000.

This directly conflicts with the precautions in the approved TMx-2000 labeling: "Attention by a qualified physician is required during the use of the TMx-2000 system. The control unit display must be monitored and controlled during the course of a therapy session to make sure that the RX-200 Applicator and rectal temperatures are within prescribed treatment parameters. Failure to monitor and deliver the TMx-2000 System procedure per recommendations by TherMatrx, Inc. may lead to decreased patient safety and/or reduced clinical effectiveness."

Because you do not have FDA approval for these new indications for use, marketing your product is a violation of the law. In legal terms, the product is adulterated under section 501(f)(1)(B) of the Act.

**Unsubstantiated Effectiveness Claims**

In addition to the above violations of the Act, we have also identified unsubstantiated promotional claims.

1. The promotional literature states that the TMx-2000 provides "4-Plus Years Durability" and "proven 5-year durability." Our review of P000043 is based on 1-year data. We have not reviewed data establishing that treatment with the TMx-2000 System is effective for 4 to 5 years. As a result, it appears that your claim may be false or misleading. If you have data demonstrating that the claim is not false or misleading, please submit it with your response to this letter.

2. The promotional literature claims the TMx-2000 "Causes Permanent Tissue Necrosis." While all thermotherapy catheters result in necrosis, this does not stop BPH tissue from forming again. To the extent that a claim of "permanent tissue necrosis" implies Thermatrx will provide a permanent cure of the patient's BPH, it is misleading. Please clarify the meaning of your claim of "permanent tissue necrosis."

3. The promotional literature claims "Superior Peak Flow Rate Improvement" for the TMx-2000. This claim also may be false and misleading since we are not aware of data establishing a statistically significant improvement over other therapies. If you have data that establishes the truthfulness of your claim of superiority, please submit it with your response to this letter.

**Conclusion and Requested Action**

In summary, as noted above, the following claims require PMA supplement approval: treatment of enlarged median lobes and treatment without constant physician monitoring. In addition, unless you can provide substantiation for the claims of 4-5 year durability of treatment; permanent tissue necrosis; and superior effectiveness as compared to other thermotherapy devices, the TMx-2000 is misbranded in violation of § 502(q) of the Act.

CDRH requests that Thermatrx immediately cease dissemination of these violative promotional materials for the TMx-2000. Please submit a written response within 15 days of receiving this letter stating whether you intend to comply with this request, listing all violative promotional materials for the TMx-2000 such as those described above, and explaining your plan for discontinuing use of such materials. Because the violations described above are serious, we request, further, that your submission include a plan of action to disseminate truthful, non-misleading, and complete information to the audience(s) that received the violative promotional materials. Please direct your response to Mr. Paul Tilton, HFZ-322, 2094 Gaither Road, Rockville, MD 20850, facsimile at 301-594-4638. In all future correspondence regarding this matter, please refer to OC Track # 94228 in addition to the PMA number. We remind you that only written communications are considered official.

To discuss specific details of a premarket submission please contact the Office of Device Evaluation, Division of Reproductive, Abdominal, and Radiological Devices (DRARD) at 301-594-5072.

The violations discussed in this letter do not necessarily constitute an exhaustive list. It is your responsibility to ensure that your promotional materials for TMx-2000 comply with each applicable requirement of the Act and FDA implementing regulations.

Failure to correct the violations discussed above may result in FDA regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Paul Tilton at (301) 594-4611.

Sincerely yours,

Timothy A. Ulatowski
Director
Office of Compliance
Center for Devices and
Radiological Health